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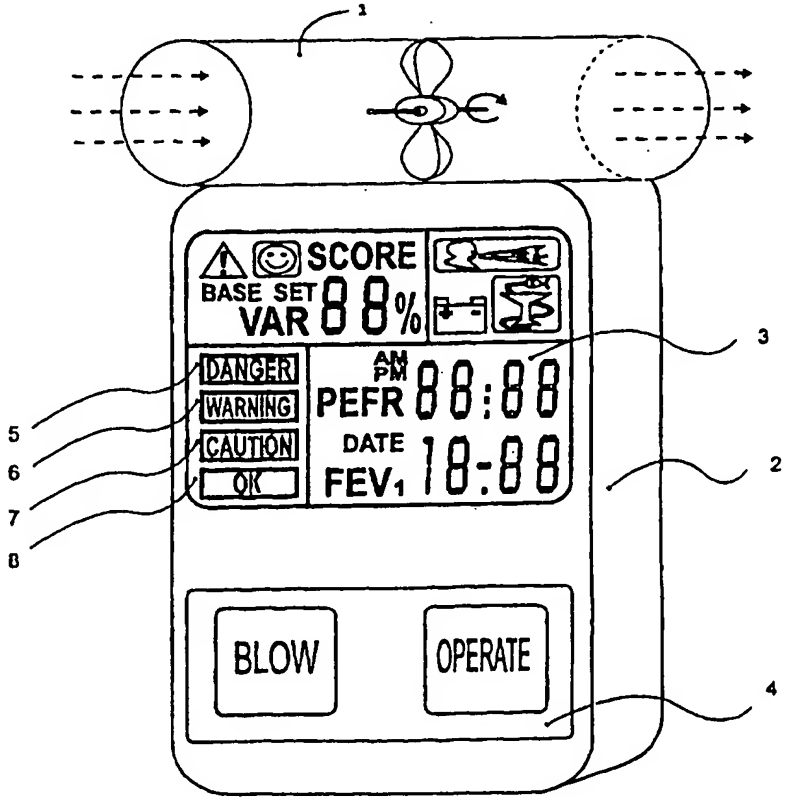
(54) Title: ELECTRONIC SPIROMETER

(57) Abstract

A portable electronic spirometer (2), indicating in real time the state of health of a patient with respiratory problems. The device comprises an air flow sensor (1), a microprocessor control (14) to perform calculations of measured data, data storage, means for calculating the best measured result over a period of time, means for establishing a base figure and for displaying results and indicating the gradient level of measurements compared with previous data stored in the memory, and means to display results (3). Also a method for electronically measuring the exhaled air peak/flow of a patient, which comprises establishing basic comparative parameters of a patient by recording results in the evening and in the morning, calculating the ratio between these, storing these in a memory, and using this data for establishing the condition of a patient by such measurements on a day the patient does not feel well.



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# ELECTRONIC SPIROMETER

## Field and Background of the Invention

The invention relates to a portable electronic device, based on exhaled peak flow air measurement for home asthma monitoring and management. The correct management of asthma is ensured when careful attention is given to the individual patient's pulmonary function and selected information from the medical history, physical examination and laboratory test results. It is important to recognize that patients with asthma are heterogeneous and the condition varies widely from patient to patient, as well as for each patient over periods of time. The clinician needs to create an individualized ongoing data base that helps assess the degree of severity of the patient's asthma, identify etiologic and aggravating factors and plan an appropriate course of therapy.

The most practical method for obtaining objective measurements of pulmonary function is by means of a spirometer. Measurements obtained with a spirometer may include PEFR and FEV1. PEFR (peak expiratory flow rate) which is the maximum flow rate that can be generated during a forced expiratory cycle with fully inflated lungs. PEFR is measured in liters per second and requires maximum effort for accuracy. FEV1 (forced expiratory volume in 1 second) is the volume of air expired in 1 second from maximum inspiration.

Portable mechanical peak flow meters are inexpensive, simple to use and easy for patients to understand. The National Institute of Health, USA, recommends that clinicians consider using home PEFR measurements to monitor the course of asthma and response to therapy in patients over 5 years old with moderate to severe asthma.

When patients learn how to take PEFR measurements at home, the clinician's ability to provide effective treatment is improved. Daily monitoring of PEFR helps, for example, in detecting early stages of airway obstruction; assessing circadian variations of lung function, providing objective criteria in planning, initiating or terminating treatment; facilitating communication between patient and clinician; and investigating specific allergens or school or workplace exposures that may exacerbate symptoms.

However, the existing mechanical peak flow meters are not accurate In comparison to the electronic spirometers that physicians use in their offices. When the physician transforms the highly accurate results of the patient's "best performance", there are discrepancies between the real nominal best performance and the best performance obtained from the mechanical peak flow meter used by the patient.

In addition to this problem , the physician has to manually calculate drops from the best performance and to manually mark it on the scale of the mechanical peak flow meter which leads to poor accuracy and relies on the personal accuracy of the physician.

When using a mechanical peak flow meter, all records of the patient's condition, over the period of time between visits, are done manually, which is inaccurate , inconvenient and not reliable.

**Summary of the Invention**

The invention provides an electronic instrument that makes it possible to automatically measure and collect data on the patient condition, calculate and indicate to the patient and physician his medical condition and, if needed, to indicate the recommended dosage of medications.

For providing these functions, the electronic device includes a peak flow sensor and microprocessor control unit with keyboard and display.

The present invention relates to a portable electronic system, for exhaled peak flow air measurements, for home asthma management, comprising air flow sensing means, microprocessor control means to perform calculations of measured data, means for storing measured results and means for calculating the best measured result over a period of time, means for recording a base figure, and for displaying results on an indicator with a traffic light type or any other indicator, means to indicate the gradient level of measurements, compared with previous measurements stored in the memory means and means to display results on a LCD in quantitive figures, such as liters per second and percentages. Advantageously it contains means for calculating differences between morning and evening "best performance" of measurements, means for storing results of calculations in memory and means for indicating on an indication system variability by percentage translated into graphic icon indicators, indicating normal or unsatisfactory condition of the patient.

A preferred embodiment comprises automatic calculating means for calculating the patient's condition by current measurement data, personal best measurement stored in memory and current variability calculation means to display the result on a color zone traffic light indicator and also variability icon indication means, which can be preset to default values which may be changed and reset by the physician according to a patient's condition.

The invention further relates to a method for electronically measuring the exhaled peak flow air measurement of a patient which comprises establishing basic comparative parameters of a patient by establishing best measured

results in the evening and in the morning, calculating the ratio between these, storing these in memory means, such measurements being based on a number of days, and subsequently using these data for establishing the real time condition of the patient by effecting such measurements on a day the patient does not feel well, and comparing the data on such day with the base values, indicating the status of the patient. Preferably the resulting data are displayed on a "good" or "bad" indicator, or on a color display similar to colors of a traffic light, different colors indicating the status of the patient.

Hitherto generally the physician carried out the measurement of the respiratory data with a sophisticated, expensive and highly accurate instrument. The patient has generally at his disposal a very simple and rather inaccurate spirometer, and the comparison of the data of these two instruments is of no great practical value. The present invention overcomes this to a large extent, as there is provided a rather inexpensive electronic instrument, with a wide range of capabilities, of high accuracy and with many automatic settings, memory, etc.

One of the principles of the measurements of the invention is that one reading is taken in the evening, which gives a relatively high value, and another in the morning, which gives a lower value. The ratio between these is generally lower than 1, and often in the 0.9 range.

If the ratio is substantially lower than 0.9, this is indicative of a rather poor state of the health of the patient.

Because many patient's values are consistently higher or lower than average predicted norms, it is important for each patient to establish a personal "best PEFR value". This personal "best value" will be the standard against which

subsequent measurements are evaluated by the patient and clinician. Personal best values can be established during an initial period in which the patient records PEFR values at least twice a day. To help asthma patients use home PEFR monitoring, the device indicates a patient's values as colored PEFR zones similar to traffic lights. The zones can be established as a function of the patient's personal best. It is recommended that daily measurements for establishing the personal best be made at least for a few days in the morning and evening. If the patient takes an inhaled medication, PEFR should be measured both before and after treatment. When the zone system is adapted to a traffic light system, it is easier to use and remember: **Green** - (80 to 100 percent of personal best) signals all clear. No asthma symptoms are present, and the routine treatment plan for maintaining control can be followed. For patients on chronic medications, consistent readings in the green zone may indicate an opportunity to consider a reduction in medications.

**Yellow** - (65 to 80 percent of personal best) signals caution. An exacerbation may be present and a temporary increase in medication may be indicated. Alternatively, the overall asthma may not be under sufficient control and maintenance therapy may need to be increased.

**Orange** - (50 to 65 percent of personal best) signals warning! An acute exacerbation may be present and a temporary increase in medication may be indicated. Alternatively, the overall asthma may not be under sufficient control and maintenance therapy may need to be increased.

**Red** - (below 50 percent of personal best) signals a medical alert. An immediate bronchodialator should be taken and the clinician should be

notified if PEFR measurements do not return immediately and stay in yellow or green zones.

**Main device features:**

**Measured parameters:**

1 Peak Expiratory Flow Rate (PEFR) displayed as a "traffic light" and also numerically.

2 Volume of Air Expired within 1 second (FEV1).

3 Variability, defined as percentage of difference between Evening and Morning measurements of PEFR.

**Values stored in memory:**

1 Personal Best

2 PEFR

3 $FEV_1$

4 Variability

5 "Make measurement" alarm

6 "Take medicine" alarm

**Operations**

Operation of the device is determined by pressing different combinations of the two keys: "**BLOW**" and " **OPERATE**".

1 "**BLOW**" - used to start measurement.

2 "**OPERATE**" - used to change the operating modes of the device.

3 Pressing both keys ("**BLOW**" & "**OPERATE**") together puts the device into the Set Mode.

**Measuring functions:**

1 Personal Best

1.1 The Personal Best is the best performed of evening exhalation of air over a period of at least 3 days of measurement (i.e. maximum PEFR value of 3 mornings).

1.2 The device continues to check if the PEFR measurement has continued for at least 3 days, otherwise, the measuring process is repeated until a Personal Best has been established.

1.3 The user has the possibility to reset the stored Personal Best in the Set Mode. After reset, new Personal Best is established as described above.

1.4 The PEFR Color Indicator function shows the comparitive result between the measured PEFR values and the Personal Best of PEFR.

2 Variability

2.1 Variability is defined as percentage of difference between evening and morning measurements of PEFR.

2.2 For evening or PM time, the LCD will display both the percentages and a graphic symbol indicating the variability of PEFR of that day.

3 Alarm setting

Alarms can be switched "ON" or "OFF" by the user in the set mode. Default alarm setting is "OFF"

3.1 **" Make Measurement"** alarm.

3.1.1 Alarm time is set automatically by the device, depending on results of user measurements (User Color Zone):

- Green Zone -- 7 AM, 5 PM
- Yellow Zone -- 7 AM, 5 PM and bedtime (10 PM)
- Orange Zone -- every 4 hours
- Red Zone -- custom, per physician's instructions

3.1.2 For convenience, all alarm time settings can be changed by the user in the Set Mode.

3.1.3 At the designated time the alarm turns "ON"- the alarm sounds and then starts timing for measurement.

3.2 **"Take Medicine"** alarm

3.2.1 Alarm is set automatically by device, depending on results of user measurements (User Color Zone):

Necessary medicine dose, depending on one of the medicine types stored in the memory in relation to the results of previous measurements or according to physician's instructions is displayed on the LCD of the device when this alarm sounds.

3.2.2 The medicine type is selected by user in the "SET" mode as per his physician's recommendation.

**Alarms features**

The device features an alarm clock with calendar having two independent settings of alarms with different sounds and indications:

1 **"Make Measurement"** alarm - informs the user to make current measurement (Up to 12 time settings per day depending on results of previous measurements or doctor instruction).

2 **"Take Medicine"** alarm - informs the user to take current medicine.

2.1 Necessary medicine dose, depending on one of the medicine types stored in the memory in relation to the results of previous measurements or according to physician's instructions is displayed on the LCD of the device when this alarm sounds.

2.2 The medicine type is selected by user in the "SET" mode as per his physician's recommendation.

**Operation process**

The device is always in Standby Mode with Clock, Calendar and Alarms until the "Make Measurement" alarm or the "BLOW" key is activated.

1 Start measurement operation either by pressing "Blow" key or switching the "Make Measurement" alarm to its set time.

2 Measurement procedure continues for 1 minute period. After 1 minute time, the device returns back to Standby Mode.

3 During measurement procedure, the user starts blowing into the meter with fully inflated lungs.

4 If the variation of PEFR or FEV1 is greater than 10%, the labels "PEFR" and "FEV1" flash simultaneously, prompting the patient to repeat the measurement.

5 If 3 consecutive measurements were performed, the PEFR and FEV1 value digits flash simultaneously, prompting the patient to stop the measurements.

6 After the measurement of PEFR and FEV1 values, the deviceacts according to the Time of Measurement :

6.1 MORNING is defined as first measurement on that day (basically 7AM)

6.1.1 LCD displays PEFR and FEV1 readings.

6.2 EVENING is defined as the evening measurement on that day (basically 5PM) in case of 2 measurements per day or as the nearest measurement to (MORNING + 8 hours), in case of more than 2 measurements per day.

6.2.1 LCD displays PEFR readings.

6.2.2 Device calculates the Variability of that day, and displays the reading:

- If Variability < 20%, then a Happy Face is displayed.
- If Variability > 20%, then an aware symbol (exclamation mark) is displayed.

7 Color Indication (Traffic Light Indication):

7.1 After measurements have continued for at least 3 days until the Personal Best (PB) of PEFR is selected, each time a future measurement is taken, the PEFR Color Indicator will compare the measured PEFR with the Personal Best and indicate one of the following colors:

**Green** - 80% to 100% of PB - "OK"

**Yellow** - 65% to 80% of PB - "CAUTION"

**Orange** - 50% to 65% of PB - "WARNING!"

**Red** - below 50% of PB - "DANGER!"

7.2 After the color indication, the meter repeats its 1 minutes timing again. If no action is taken during this time it returns to the Standby Mode.

**Detailed Description Of The Invention**

The invention will now be described in detail, having reference to the accompanying drawings wherein:

Fig. 1 is a block diagram of one embodiment of the instrument,

Fig. 2 is a block diagram of the electronic circuitry of the instrument,

Fig. 3 is a drawing of the LCD display of the instrument.

Fig. 4 is a drawing of an optional enhanced device including duplex communication capabilities and a number of preset questions to be answered by the patient to a number of preset answers by scoring ranges.

Turning first to Fig.1, the novel device comprises an air flow sensor 1, integrated to the instrument's body frame. The air flow sensor can be of any type such as winding propeller, sensor based on measuring the differences of temperatures between input and output, air pressure sensor etc. Fig.1 and Fig. 2 show the sensor based on the measurement of winding propeller velocity. The instrument 2 comprises an LCD display 3 and keyboard 4, and the required number of keys for manual control of the device. On the LCD are placed the color labels for Traffic Light indication, where :

5 - Red label

6 - Orange label

7 - Yellow label

8 - Green Label

The components of the instrument are set out in Fig. 2 and comprise the air flow sensor 9, with spinning propeller 10, sensor of velocity RPM (rate of rev. per minite) of the propeller 12 connected to the amplifier 13. When exhaled air 11 is applied to the air flow sensor 9, the propeller 10 spins, and changes the output signal of the propeller velocity sensor 12. Signal of the propeller velocity sensor 12 is amplified by amplifier 13, passes via microprocessor control unit 14 to an LCD display 16 and to memory 17. The microprocessor control unit 14 is in charge of all the automatic functions of the device, such as measurement, calculations, storing in the memory, automatic activation of alarms and displays. The keyboard 15 is used for initialization of the instrument, activates the instrument to the measurement mode and switches the instrument to other modes. The additional communication units 18 and 18' comprises a transmitter/receiver unit 19 and transmitter/receiver 20 of the remote unit, used for communication between instrument and remote unit via infra-red, RF, cable, or any other type of connection. Fig. 4 shows the enhanced device where 22 is the communication unit and 21 is the message display unit.

**Claims:**

1. A portable electronic system, for exhaled peak flow air measurements, for home asthma management, comprising air flow sensing means, microprocessor control means to perform calculations of measured data, means for storing measured results and means for calculating the best measured result over a period of time, means for recording a base figure, and for displaying results on an indicator with a traffic light type or any other indicator, means to indicate the gradient level of measurements, compared with previous measurements stored in the memory means and means to display results on a LCD in quantitative figures, such as liters per second and percentages.

2. A system claimed in claim 1 including means for calculating differences between morning and evening "best performance" of measurements, means for storing results of calculations in memory and means for indicating on an indication system variability by percentage translated into graphic icon indicators, indicating normal or unsatisfactory condition of the patient.

3. A system according to claim 2 including automatic calculating means for calculating the patient's condition by current measurement data, personal best measurement stored in memory and current variability calculation means to display the result on a color zone traffic light indicator.

4. A system according to claim 3 comprising variability icon indication means, which can be preset to default values which may be changed and reset by the physician according to a patient's condition.

5. A system as claimed in claim 3 where the colored traffic light zones have means to preset default values which may be changed and reset by the physician according to his patient's condition.

6. A system according to any of claims 1 to 5 comprising duplex communication interfaces enabling transmission and reception of data from the unit to a remote unit which is under a physician's supervision.

7. A system as according to claim 6 where preset default values of variability and user color zone cutoff values can be changed and reset by the remote unit that is under the supervision of the physician.

8. A system as claimed in any of claims 1 to 6 including automatic alarm means to remind the patient to make the required number of measurements, depending on his condition.

9. A system as claimed in any of claims 1 to 7 including a list of asthma medications and their respective dosages, stored in the memory which can be indicated by the physician from his control unit.

10. A method for electronically measuring the exhaled peak flow air measurement of a patient which comprises establishing basic comparative parameters of a patient by establishing best measured results in the evening and in the morning, calculating the ratio between these, storing these in memory means, such measurements being based on a number of days, and subsequently using these data for establishing the real time condition of the patient by effecting such measurements on a day the patient does not feel well, and comparing the data on such day with the base values, indicating the status of the patient.

11. A method according to claim 10, where the resulting data are displayed on a "good" or "bad" indicator, or on a color display similar to colors of a traffic light, different colors indicating the status of the patient.

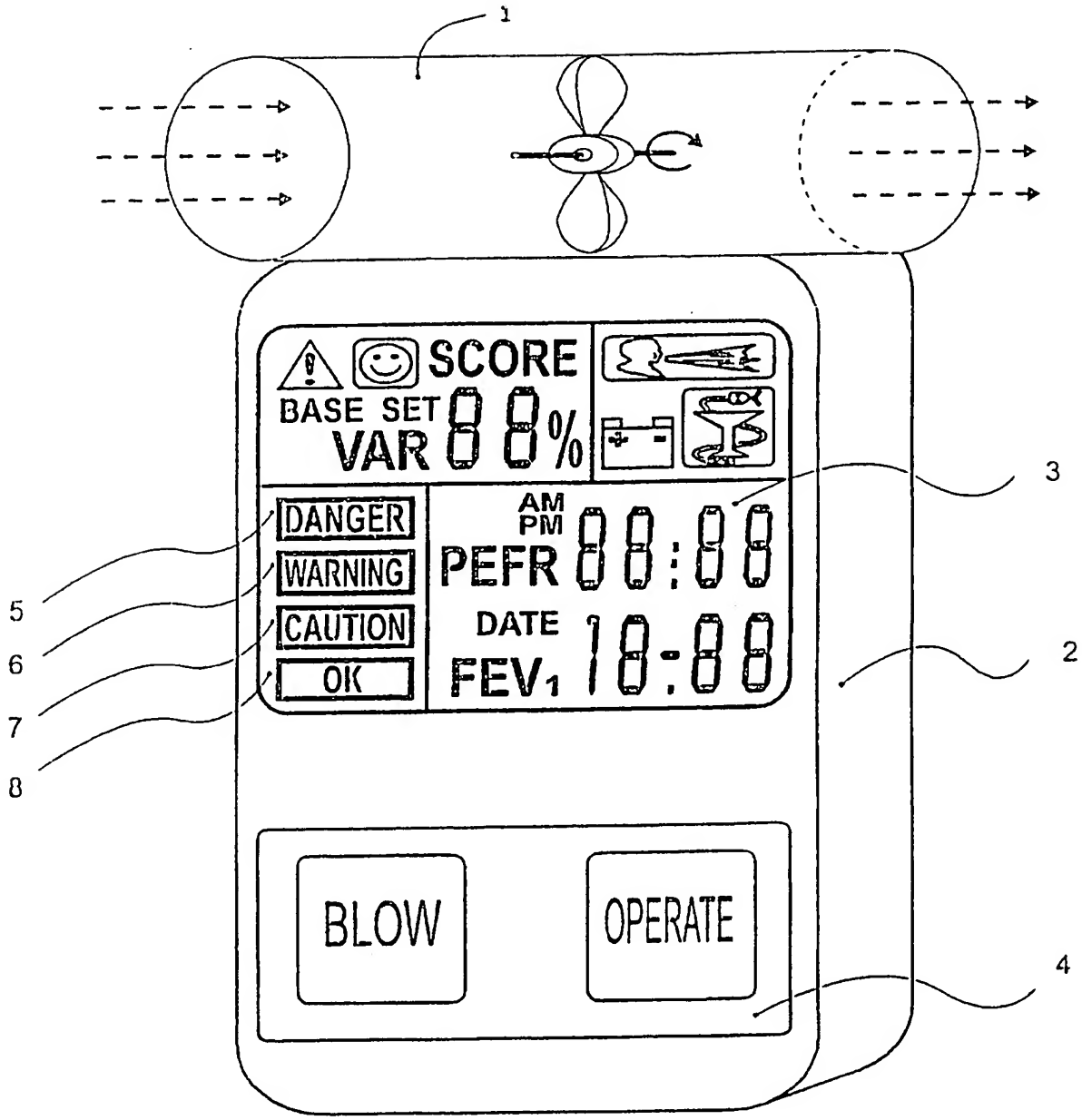
1
SCORE
BASE SET
VAR 88%
DANGER
WARNING
CAUTION
OK
AM
PM
PEFR 88:88
DATE
FEV1 18:88
BLOW
OPERATE
2
3
4
5
6
7
8

FIG.1

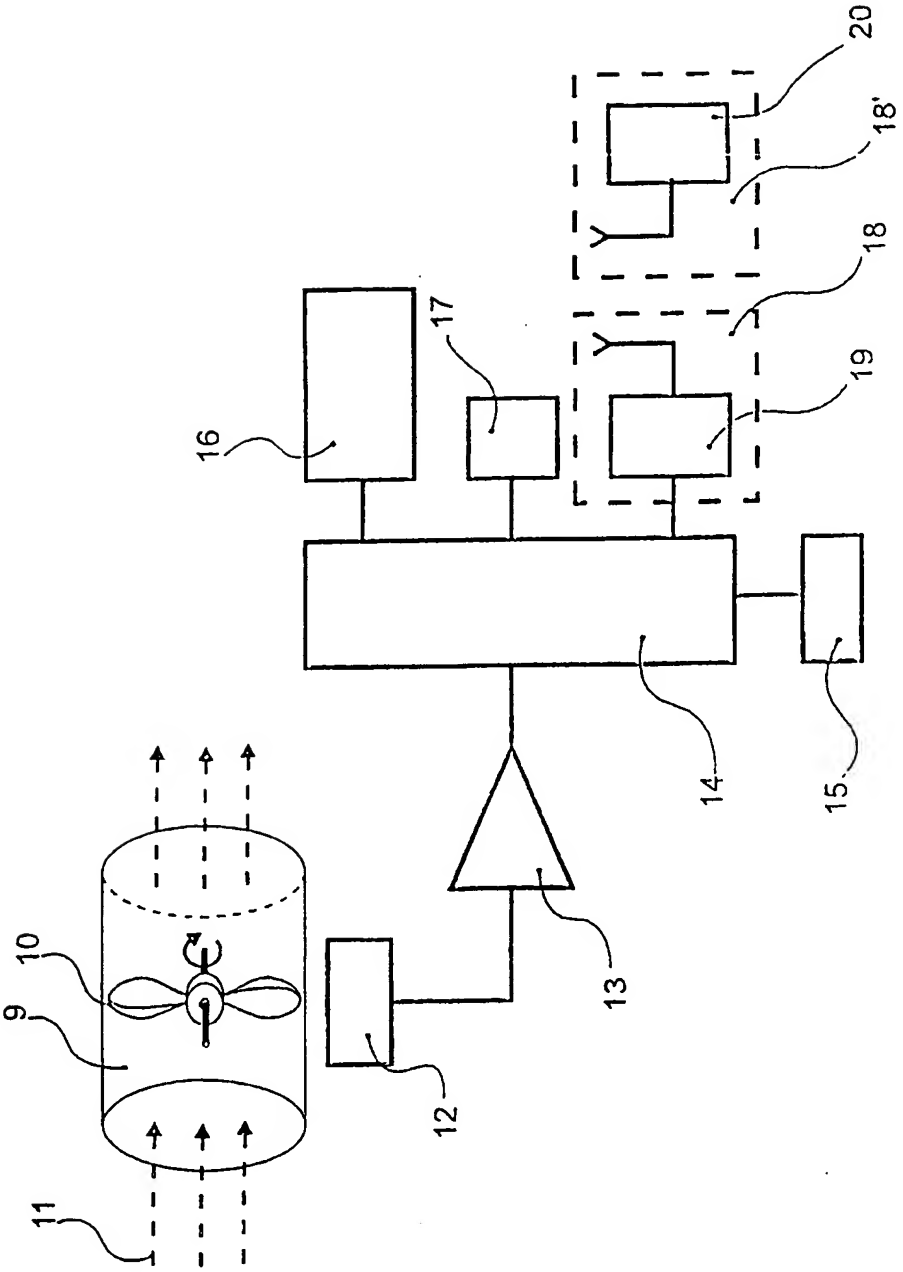


Fig. 2

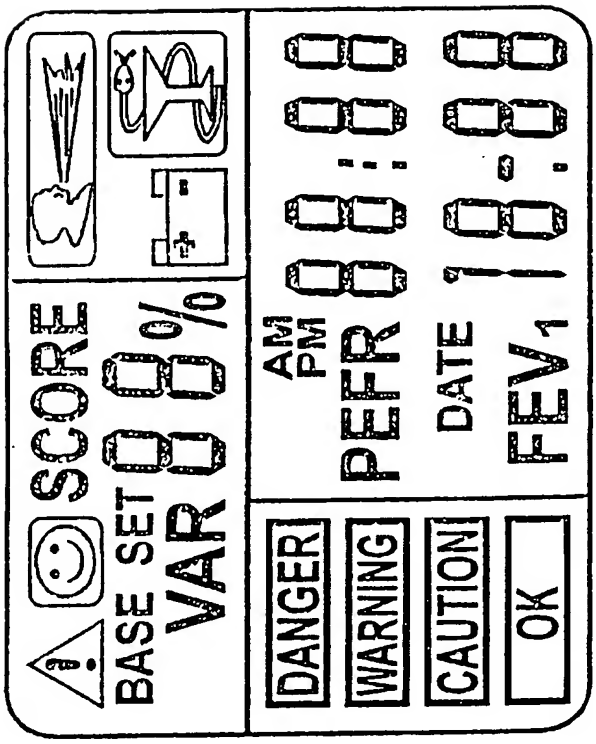
SCORE
BASE SET
VAR 00%
AM
PM
PEFR 00:00
DATE 10.00
FEV1 10.00
DANGER
WARNING
CAUTION
OK

Fig. 3

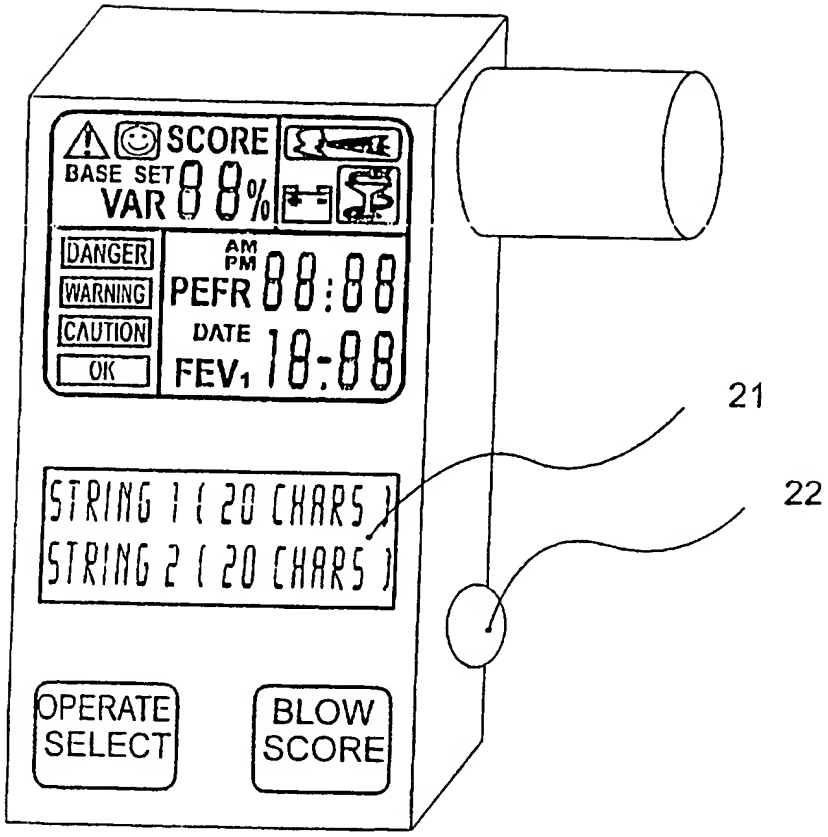
SCORE
BASE SET
VAR 88%
DANGER
WARNING
CAUTION
OK
AM
PM
PEFR 88:88
DATE
FEV1 18:88
STRING 1 ( 20 CHARS )
STRING 2 ( 20 CHARS )
OPERATE SELECT
BLOW SCORE
21
22

Fig 4

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL96/00154

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A61B 5/087
US CL :128/725

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/725-730

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

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**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
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| X<br>---<br>Y | US 5,373,851 A (REINHOLD, JR. et al) 20 December 1994, entrie document. | 1, 2<br>---<br>3, 4, 6 |
| X | US 5,058,601 A (RIKER) 22 October 1991, entire document. | 1 |
| X | US 5,137,026 A (WATERSON et al) 11 August 1992, entire document. | 1 |
| X<br>---<br>Y | US 5,277,195 A (WILLIAMS) 11 January 1994, entire document. | 1<br>---<br>6 |

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INTERNATIONAL SEARCH REPORT

International application No.
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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|---|---|---|
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| Y,P | | 3, 4, 10, 11 |
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